REMARKS

Claims 26, 27, 31 – 33 and 36 - 47 are pending in the application. Claims 26, 27, 31 – 33, 39 – 43 and 47 have been amended. Claims 1 – 25, 28 – 30, 34 – 38, and 44 – 46 have been cancelled. No new claims have been added. No new matter has been added by virtue of the amendments, support being found throughout the specification and claims as originally filed.

Claim Rejections

35 U.S.C. § 112, first paragraph

Claims 26 – 27, 31 – 33, 36 – 37, 39 – 45, 47 have been rejected under 35 U.S.C. § 112, first paragraph, for allegedly failing to comply with the enablement requirement. The Examiner argues that the "specification, while being enabling for a polypeptide or a composition comprising SEQ ID NO:6 encoded by the polynucleotide with SEQ ID NO:5 wherein the polypeptide is an enzyme which is capable of deamidating amido groups in target proteins and peptides by directly acting upon said amido groups without cutting peptide bonds and without crosslinking said target proteins or peptides, and a method for producing said polypeptide by culturing a transformed cell, transformed with a vector comprising the polynucleotide encoding the amino acid sequence SEQID NO:6 does not reasonably provide enablement for any or all such polypeptides isolated from any or all microorganisms including those listed in the above claims." (Office Action, p.2). Applicants respectfully disagree.

The instant claims have been amended such that the claims recite a polypeptide or composition comprising SEQ ID NO:6 encoded by the polynucleotide sequence of SEQ ID NO: 5. For example, instant claim 26 recites an isolated enzyme which has an activity to deamidate amido groups in a protein, wherein said enzyme comprises the amino acid sequence of SEQ ID NO:6.

As pointed out by the Examiner, Applicants have provided ample disclosure showing identification, characterization and isolation of the gene coding for the protein-deamidating enzyme derived from Chryseobacterium sp., SEQ ID NO: 6 (see, e.g. Examples 1 – 13).

Taken together with the guidance provided in the specification that shows the activity of SEQ ID NO: 5 and 6 to deamidate amido groups in a protein and the knowledge of one of skill in the art to screen for multiple substitutions or modifications as encompassed by the instant claims, Applicants submit that the instant invention is enabled as claimed. Applicants respectfully request withdrawal of the rejection and allowance of the claims.

Claims 26 – 27, 31 (a) – (b)– 33, 36 – 37, 39 – 45, 47 have been rejected under 35 U.S.C. § 112, first paragraph for allegedly containing subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time of filing, had possession of the claimed invention. Applicants respectfully traverse the rejection.

The instant claims have been described above.

The Examiner argues that the claims "are directed to any or all polypeptides having deamidase activity and isolated from various sources and polypeptides and fragments corresponding to variants, mutants and recombinants of SEQ ID NO:6 as well as method of making said polypeptide using transformed cells." (Office Action, p.7). The Examiner argues that "(n)o information, beyond the characterization of SEQ ID NO:6 has been provided by applicants, which would indicate that they had possession of the genus of polypeptides or a method of making the same." (Office Action, p.7).

The instant claims have been amended to encompass enzymes comprising the amino acid sequence of SEQ ID NO:6, and enzymes comprising the amino acid sequence encoded by the nucleotide sequence of SEQ ID NO:5. Accordingly, the instant claims are adequately described under the written description guidelines because the structure and

function of the sequences disclosed have been taught in the specification. Applicants respectfully request that the Examiner reconsider and withdraw the foregoing rejection.

Claims 38 and 46 have been rejected because the Examiner alleges that "the invention appears to employ a novel *Chryseobacterium* microorganism." (Office Action, p.9). Applicants respectfully traverse the rejection.

Instant claims 38 and 46 have been cancelled. Applicants respectfully request withdrawal of the rejection.

35 U.S.C. § 103

Claim 31 has been rejected under 35 U.S.C. § 103(a) as being unpatentable over Vaintraub et al. and Sambrook et al. (Molecular Cloning, A Laboratory Manual, 2nd Ed, Cold Spring harbor Laboratory Press, 1989, p.7.37 – 7.52). Applicants respectfully traverse the rejection.

Instant claim 31 recites a recombinant polypeptide having an action to deamidate amido groups in protein, which is obtained by culturing a transformant transformed with a recombinant vector, which contains a nucleotide being selected from the following nucleotides (i) to (iii) and encoding a polypeptide having an activity to deamidate amido groups in protein; (i) a nucleotide which encodes a polypeptide having the amino acid sequence of SEQ ID NO:6, (ii)a nucleotide which has the nucleotide sequence of SEQ ID NO:5, (iii)a nucleotide which is degenerate with respect to any one of the aforementioned nucleotides (i) to (ii).

The Examiner argues that the Vaintraub reference "teaches a deamidase which (is) inherently the same as that claimed in this application." (Office Action, p.11). The Examiner admits that "while the reference does not teach a recombinant enzyme...Sambrook et al. teach exhaustive methods of making recombinant protein starting from a purified protein." (Office Action, p.11). The Examiner alleges that "it would have been obvious to one of skill in the art "to combine the teachings of Vaintraub et al. with that of Sambrook et al. to arrive at a recombinant protein (and) one would be

motivated to do this in order to prepare large amounts of the protein...with a reasonable expectation of success since Veintraub et al. provide the protein and Sambrook et al. teach a reliable and time-tested method." (Office Action, p.11 - 12).

The Vaintraub reference does not teach or suggest **a recombinant polypeptide having an action to deamidate amido groups in protein and having the amino acid sequence of SEQ ID NO: 6 and the nucleotide sequence of SEQ ID NO:5** as recited in the instant claims. The deamidase taught by the Vaintraub reference is different from the deamidase taught in the instant invention. The Vaintraub reference describes the purification of a deamidase from germinating wheat grains "that acts on native proteins." (p.171). The Vaintraub reference describes the action of the identified deamidase of some substrates (Table II), and teaches that the enzyme "deamidated all the seed storage proteins tested (but) from the other native proteins tested only lysosome and hemoglobin showed a marked deamination." (p.171). The Vaintraub reference teaches that "the difference in sensitivity of protein substrates to the action of the deamidating enzyme is evidently determined by the content of the amidated amino acid residues (glutamyl residues if the enzyme specificity suggested is true) and their availability." (p.171). **There is no teaching or suggestion in the Vaintraub reference of a deamidase of SEQ ID NO: 5 or 6**, and given the limited teaching of the Vaintraub reference directed to a natural deamidase from germinating wheat grains, one of skill in the art would not be motivated to make a recombinant deamidase of SEQ ID NO: 5 or 6.

The teaching of the Sambrook reference does not cure the flaws of the Vaintraub reference. The Examiner argues that "Sambrook et al. teach exhaustive methods of making recombinant protein starting from a purified protein." (Office Action, p.11)." However, nowhere does Sambrook teach or suggest **a recombinant polypeptide having an action to deamidate amido groups in protein and having the amino acid sequence of SEQ ID NO: 6 and the nucleotide sequence of SEQ ID NO:5** as recited in the instant claims.

Applicants submit that no combination of the cited references teaches or suggests all limitations of the instantly claimed invention. Accordingly, Applicants respectfully request withdrawal of the rejection and allowance of the claims.

Non-statutory Double Patenting

Claims 26 – 27, 32 – 33, 36 – 47 have been rejected under the judicially created doctrine of obviousness-type double patenting over claims 1 – 3 of US Patent 6,251,651. Applicants respectfully disagree.

The instant claims have been amended as described above to recite specifically wherein said enzyme comprises the amino acid sequence of SEQ ID NO:6.

According to the MPEP at ¶ 8.32:

> A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); and *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985).

In the instant case, the claims as amended recite SEQ ID NOs 5 and 6. SEQ ID NOs 5 and 6 of the instant application are not identical to SEQ ID NOs 5 and 6 of US Patent 6,251,651.

Upon allowance of the claims, Applicants will file a terminal disclaimer to obviate any remaining obviouness type double patenting rejections.

Applicants respectfully request withdrawal of the rejection and allowance of the claims.

35 U.S.C. § 101, Double Patenting

Claim 31 has been rejected under 35 U.S.C. § 101 as claiming the same invention as that of claims 1 – 3 of prior US Patent No. 6,251,651. Applicants respectfully traverse the rejection.

Instant claim 31 recites a nucleotide which encodes a polypeptide having the amino acid sequence of SEQ ID NO:6 and a nucleotide which has the nucleotide sequence of SEQ ID NO:5. As described above, SEQ ID NOs 5 and 6 of the instant application differ from SEQ ID NOs 5 and 6 of US Patent 6,251,651.

According to the MPEP

> In determining whether a statutory basis for a double patenting rejection exists, the question to be asked is: ***Is the same invention being claimed twice?*** 35 U.S.C. 101 prevents two patents from issuing on the same invention. **"Same invention" means identical subject matter**. *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1984); *In re Vogel,* 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957). [MPEP, Chapter 800; emphasis added]

In the instant case, the SEQ ID NOs 5 and 6 of the instant application and the 6,251,651 patent are not the same, and thus the same invention is not being claimed twice.

Under the training materials, the MPEP advises the Examiner to consider:

> Is there an embodiment of the invention ***that falls within the scope of one claim, but not the other***? If there is such an embodiment, then identical subject matter is not defined by both claims and statutory double patenting would not exist. For example, the invention defined by a claim reciting a compound having a "halogen" substituent is not identical to or substantively the same as a claim reciting the same compound except having a "chlorine" substituent in place of

the halogen because "halogen" is broader than "chlorine." [MPEP, Chapter 800; emphasis added].

In the instant case, identical subject matter is not defined by claim 31 of the instant application and claims 1 – 3 of the 6,251,651 patent because SEQ ID NOs 5 and 6 are different. Accordingly, the double patenting rejection is improper.

Applicants respectfully request withdrawal of the rejection and allowance of the claims.

CONCLUSIONS

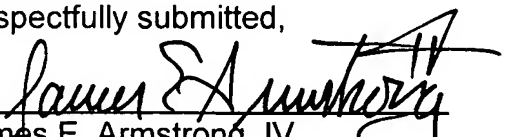
In view of the above amendment and remarks, Applicants believe the pending application is in condition for allowance.

Should the Examiner wish to discuss any of the amendments and/or remarks made herein, the undersigned attorney would appreciate the opportunity to do so.

The Director is hereby authorized to charge any credits or deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 04-1105.

Dated: November 13, 2007

Respectfully submitted,

By 

James E. Armstrong, IV
Registration No.: 42,266
EDWARDS ANGELL PALMER & DODGE LLP
P.O. Box 55874, Boston, MA 02205
(202) 478-7370
Attorneys/Agents For Applicant